EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance sulfuryl fluoride

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[1], and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2010/38/EU[2] of 18 June 2010 amending Council Directive 91/414/EEC to include sulfuryl fluoride as active substance provides further confirmatory information on estimates of sulfuryl fluoride atmospheric lifetime, the tropospheric concentrations of sulfuryl fluoride and the milling conditions, necessary to ensure that residues of fluoride ion in cereals do not exceed the natural background levels.

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[3].

(3) The notifier submitted additional information with a view to confirm the risk assessment for the fate of sulfuryl fluoride in the atmosphere and for the residues of fluoride ion in milling products present in the machinery during the fumigation.

(4) The United Kingdom assessed the additional information submitted by the notifier. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission, and the European Food Safety Authority, hereinafter 'the Authority', on 4 June 2015.

(5) The Commission considered that according to the additional information provided by the notifier, it could not be excluded that the residue levels in milling products present in the machinery during the fumigation will exceed the natural background concentration for fluoride ion or will not meet the relevant maximum residue levels. Therefore the conditions of approval should be amended to ensure that milling

[1] OJ L 309, 24.11.2009, p. 1.

[2] Commission Directive 2010/38/EU of 18 June 2010 amending Council Directive 91/414/EEC to include sulfuryl fluoride as active substance (OJ L 154, 19.6.2010, p. 21).

[3] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

products present in the treated facilities always comply with provisions of Regulation (EC) No 396/2005.

Furthermore it considered that the information submitted has not demonstrated the steady state of sulfuryl fluoride in troposphere; consequently there is also a need for further monitoring of its tropospheric concentrations until the steady state is fully proven. It is also appropriate to provide for the further monitoring the tropospheric concentrations of sulfuryl fluoride and to submit information in this regard to the Commission, Member States and the European Food Safety Authority on regular basis, every fifth year.

(6) Sulfuryl fluoride is also approved as a biocidal active substance according to Commission Directive 2009/84/EC[4] of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto. Due to the same concerns about the environmental fate of sulfuryl fluoride as for the pesticidal uses, additional information including a monitoring of the tropospheric concentrations has been required. Submission dates of information should be the same, in order to avoid redundant work and rationalize the evaluation process.

(7) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(8) The applicant was given the possibility to submit comments on the review report.

(9) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing sulfuryl fluoride which are not complying with the restricted conditions of approval.

(10) For plant protection products containing sulfuryl fluoride, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EC) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

[4] Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (OJ L 197, 29.7.2009, p. 67)

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing sulfuryl fluoride as active substance by [6 months after EIF].

Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 12 months after restriction or withdrawal of the respective authorisation at the latest.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude Junker